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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,234	08/08/2003	Jacques Van Snick	LUD 5582.1 DIV (10019655)	4108
24972 7590 09/27/2005 FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			EXAMINER MERTZ, PREMA MARIA	
			ART UNIT 1646	PAPER NUMBER
DATE MAILED: 09/27/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/638,234

Applicant(s)

VAN SNICK ET AL.

Examiner

Prema M. Mertz

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1-2, 5-14, are drawn to a method of treating or preventing a pathologic disorder by administering an IL-4 conjugate, classified in Class 424, subclass 85.2.

Group 2. Claims 1-2, 5-14, are drawn to a method of treating or preventing a pathologic disorder by administering an IL-5 conjugate, classified in Class 424, subclass 85.2.

Group 3. Claims 1-15, are drawn to a method of treating or preventing a pathologic disorder by administering an IL-9 conjugate, classified in Class 424, subclass 85.2.

Group 4. Claims 1-2, 5-14, are drawn to a method of treating or preventing a pathologic disorder by administering an IL-13 conjugate, classified in Class 424, subclass 85.2.

Group 5. Claims 16-17, are drawn to a method of treating eosinophila or allograft rejection by administering an autoantibody to IL-9, classified in Class 424, subclass 139.1.

Group 6. Claims 18-19, 22, 24-29, are drawn to a method of inducing an elevated titre of an antibody by administering a conjugate of IL-4, classified in Class 424, subclass 85.2.

Group 7. Claims 18-19, 22, 24-29, are drawn to a method of inducing an elevated titre of an antibody by administering a conjugate of IL-5, classified in Class 424, subclass 85.2.

Group 8. Claims 18-29, are drawn to a method of inducing an elevated titre of an antibody by administering a conjugate of IL-9, classified in Class 424, subclass 85.2.

Group 9. Claims 18-19, 22, 24-29, are drawn to a method of inducing an elevated titre of an antibody by administering a conjugate of IL-13, classified in Class 424, subclass 85.2.

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Group 10. Claims 30-35, 37, 39, are drawn to a method of determining the efficacy of an agent by administering an immunogenic conjugate of IL-4, classified in Class 424, subclass 85.2.

Group 11. Claims 30-35, 37, 39, are drawn to a method of determining the efficacy of an agent by administering an immunogenic conjugate of IL-5, classified in Class 424, subclass 85.2.

Group 12. Claims 30-38, 39, are drawn to a method of determining the efficacy of an agent by administering an immunogenic conjugate of IL-9, classified in Class 424, subclass 85.2.

Group 13. Claims 30-35, 37, 39, are drawn to a method of determining the efficacy of an agent by administering an immunogenic conjugate of IL-13, classified in Class 424, subclass 85.2.

Group 14. Claims 40-43, are drawn to an immunoconjugate of IL-9 and a carrier, classified in Class 424, subclass 85.1.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups 14 and 3, 5, 8, 12, are related as product and processes of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the inventions are distinct because the products may be used in the claimed methods, or as antigen to bind and purify antibodies in immunochromatography.

Inventions 1-13 are independent and distinct, each from the other, because the methods are practiced with materially different process steps with materially different starting materials and each method requires a non-coextensive search because of different starting materials,

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process steps and goals. For example the method of Group I encompasses administering an IL-4 conjugate, however, the method of Group II encompasses administering an IL-5 conjugate. A search for each of these specific conjugates would not necessarily reveal art pertinent to the other and would require separate searches.

Furthermore, with respect to inventions 1-13, the novelty of the inventions lies in the products being administered and not the processes. The only feature in common in the instant inventions is "the method of treating", which does not constitute the special technical feature lacking from the prior art because this method can be used with a composition other than the instant products such as IL-6. Distinctness is further shown because each of these products in each method can be made and used without any one or more of the other products. The products in the different Groups are physically, chemically and biologically distinct from each other, and if patentable would support separate patents. Furthermore, separate search terms would be required for searching the literature, eg. a search of the literature for an association of IL-9 conjugate with eosinophilia would not necessarily reveal art for an association of IL-13 with eosinophilia.

Inventions 14 and 1-2, 4, 6-7, 9-11, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions are not disclosed as capable of use together.

### ***Election of Species***

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2. This application contains claims directed to the following patentably distinct species of the claimed invention:

If Groups 1-5 are elected, Applicants are required to elect one of the following species of pathologic disorder;

(i) lymphomagenesis;

(ii) autoimmune diabetes;

(iii) asthma;

(iv) mast cell activation;

(v) eosinophilia; and

(vi) allograft rejection.

If Groups 1-13 are elected, Applicants are required to elect one of the following species of carrier:

(i) ovalbumin (OVA);

(ii) a substituted OVA;

(iii) KLH;

(iv) acetylated BSA; and

(v) pertussis toxin.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 7-13, 18, 23, 25-29, 30, 32-34, 39 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

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thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the



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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the



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product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Prema Mertz*  
Prema Mertz Ph.D.  
Primary Examiner  
Art Unit 1646  
June 28, 2005